REPORT

DETERMINATION OF THE PYROPHORIC PROPERTIES OF

[redacted]

NOTOX Project 336599
NOTOX Substance 111834

CONFIDENTIALITY STATEMENT

This report contains the unpublished results of research sponsored by [redacted]. Reproduction, issue or disclosure to third parties in any form is not permitted without prior written authorisation from the sponsor.

STATEMENT OF GLP COMPLIANCE

NOTOX B.V., 's-Hertogenbosch, The Netherlands

The study described in this report has been correctly reported and was conducted in compliance with the most recent edition of:

The OECD Principles of Good Laboratory Practice

which are essentially in conformity with:

The United States Food and Drug Administration. Title 21 Code of Federal Regulations Part 58.

The United States Environmental Protection Agency (FIFRA). Title 40 Code of Federal Regulations Part 160.

The United States Environmental Protection Agency (TSCA). Title 40 Code of Federal Regulations Part 792.

Study Director

Ing. H.J. Krips

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Date: 14 November 2001

Management

Dr. Ir. H. Willems
Head of Chemistry

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Date: November 20, 2001

QUALITY ASSURANCE STATEMENT

NOTOX B.V., 's-Hertogenbosch, The Netherlands

This report was audited by the NOTOX Quality Assurance Unit to ensure that the methods and results accurately reflect the raw data.

The dates of Quality Assurance inspections and audits are given below.
During the on-site inspections procedures applicable to this type of study were inspected.

DATES OF QAU INSPECTIONS/AUDITS	REPORTING DATES
on-site inspection (s)	
4-Sep-2001 to 11-Sep-2001 (process)	13-Sep-2001
protocol inspection (s)	
03-Oct-2001 (study)	03-Oct-2001
report audit (s)	
16-Oct-2001 to 17-Oct-2001 (study)	17-Oct-2001

Head of Quality Assurance
C.J. Mitchell B.Sc.

Date: 20-NOV-01

SUMMARY

The determination of the pyrophoric properties of [redacted] was performed in accordance with EEC-Directive 92/69 EEC, A.13 "Pyrophoric properties of solids and liquids".

No ignition occurred within five minutes, after adding the test substance to celite and no ignition or charring was observed within five minutes after adding the test substance to a filter paper.

In conclusion, [redacted] has not to be classified "Pyrophoric" according to the criteria in the method A.13 of EEC-Directive 92/69 EEC.

PREFACE

Sponsor	[redacted]
Study Monitor	Dr. C.L.J. Braun SHERA, Regulatory Affairs Department
Testing Facility	NOTOX B.V. Hambakenwetering 7 5231 DD 's-Hertogenbosch The Netherlands
Study Director	Ing. H.J. Krips
Study Plan	Start : 15 October 2001 Completed : 15 October 2001

TEST SUBSTANCE

Identification	[redacted]
Chemical name	[redacted]
CAS RN	Not yet assigned
Description	Clear colourless liquid
Batch	[redacted]
Purity	Treat as 100% pure
Test substance storage	In refrigerator in the dark
Stability under storage conditions	Not indicated
Expiry date	12 July 2002 (allocated by NOTOX, 1 year after receipt of the test substance)

The sponsor is responsible for all test substance data unless determined by NOTOX.

PURPOSE

The purpose of the study was to evaluate the pyrophoric properties of the test substance.

GUIDELINES

The study procedures described in this report are based on the following guideline:

European Economic Community (EEC), EEC-Directive 92/69 EEC, Part A, Methods for the determination of physico-chemical properties, A.13 "Pyrophoric properties of solids and liquids", EEC Publication No. L383, December 1992.

ARCHIVING

NOTOX B.V. will archive the following data for at least 10 years:
protocol, report, test substance reference sample and raw data. Thereafter, no data will be withdrawn without the sponsor's written consent.

TEST SYSTEM AND RATIONALE

Test system	As inert material, celite 545 with particle size 0.02-0.1 mm (Merck; Darmstadt, Germany) was used.
Conditions	The test was performed in a fume cupboard.
Rationale	Recognized by the international guidelines as recommended test system (EEC).

PERFORMANCE OF THE TEST

A porcelain cup was filled with celite 545 (Merck; Darmstadt, Germany) to a height of approximately 5 mm. 5 ml of the test substance was poured into the cup from a height of 5 cm and stirred, to mix the test substance with the celite 545.
Observations were made to determine whether ignition of the test substance occurred within the next 5 minutes.
The test was performed in 6-fold under ambient conditions.

Because no ignition occurs, in the six tests the following test was performed three times:
A 0.5 ml test substance sample was delivered from a syringe to an indented filter paper (S&S, 589 Black ribbon, Φ 90 mm). Observations were made to determine whether ignition or charring of the filter paper occurs within five minutes.

During the tests, the temperature in the fume cupboard was measured.

DATA HANDLING

If in one of the tests, ignition (or charring of the filter paper) occurred within 5 minutes, the test substance is considered to be pyrophoric.

RESULTS

No ignition occured within five minutes, after adding the test substance to celite and no ignition or charing was observed within five minutes after adding the test substance to a filter paper.

The temperature in the fume cupboard was measured to be 21°C.

From this it is concluded that [redacted] is not pyrophoric, under the conditions of the test.

[redacted]

CERTIFICATE OF ANALYSIS

[redacted]

Certificate of Analysis [redacted]

ICS-331

Product name : [redacted]

Chemical name : [redacted]

Batch number : [redacted]

Test results:

Method	Analysis of	Unit	Result *1
Col/86.2, Jo/95.2	Peroxidic compounds (sum) ***See page 2 for a specification***	% m/m	28.9 (± 1.5)
J20010381	Dimethyl phthalate	% m/m	66.0 (± 1.0)
J20010381	Methyl isopropyl ketone	% m/m	2.7 (± 0.3)
Amp/88.9	Water	% m/m	2.8 (± 0.3)
J20010381	Unidentified impurities	% m/m	0.5 (± 0.2)

*1 bracketed values are estimated 95% confidence intervals

File code : **TNA-2001004**

Analytical documentation : 20010381

Authorized by

Name : [redacted]
Function : [redacted]
[redacted] August 7, 2001

Signature : [redacted]

[redacted]

[redacted]

Certificate of Analysis

[redacted]

[redacted] batch [redacted]: specification of the peroxidic compounds

structure	% m/m
[redacted]	[redacted]
	[redacted]
	[redacted]

[redacted]